DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

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[Docket No. 2002N–0276]

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; reopening of comment period

SUMMARY: The Food and Drug Administration (FDA) is reopening for 30 days, on a limited set of issues, the comment period on the Registration of Food Facilities Interim Final Rule (IFR) that appeared in the **Federal Register** of October 10, 2003 (68 FR 58894). The IFR requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. FDA is taking this action consistent with its statement in the IFR that it would reopen the comment period for 30 days in March 2004 to ensure that those commenting on the IFR have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the registration program.

DATES: Submit written or electronic comments on the identified set of issues for the IFR by [*insert date 30 days after date of publication in the* **Federal Register**].

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ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894), FDA issued an IFR to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The registration regulation requires facilities that manufacture/process, pack, or hold food (including animal feed) for consumption in the United States to register with FDA by December 12, 2003. In the "Request for Comments" section of the IFR, FDA requested comments on specific issues in order to improve the assumptions used in its economic analysis. The IFR stated that its comment period would coincide with that of the prior notice IFR, given the relatedness of the two rules. Therefore, the registration IFR was open for comments for 75 days following the publication of the IFR. The IFR also stated that "to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule," FDA would reopen the comment period for an additional 30 days in March 2004.

II. Comments

Consistent with the intent expressed in the preamble to the IFR, we are seeking comments on the following issues in order to improve FDA's economic analysis:

1. The cost to foreign facilities of hiring and retaining a U.S. agent. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The costs to a foreign facility of hiring a U.S. agent;

b. The number of foreign facilities that have hired a U.S. agent or negotiated additional duties from someone with whom they have an existing relationship, in response to the IFR, instead of relying on an existing relationship with a person who qualifies as a U.S. agent;

c. The number of foreign facilities that have ceased exporting to the United States because they have decided not to hire/retain a U.S. agent for registration purposes;

d. The distribution of costs between submitting registrations and other services offered by the U.S. agent; and

e. The assumptions underlying FDA's estimates of the costs of hiring and retaining a U.S. agent.

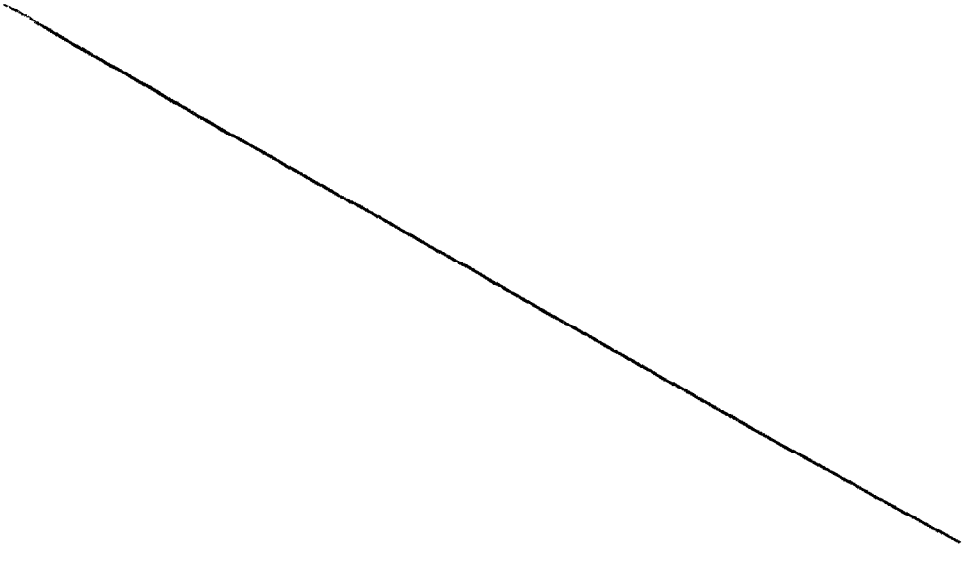
2. The effects on domestic small businesses, if any, if some foreign facilities cease exporting to the United States due to the U.S. agent requirement for registration. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration; and

b. The costs incurred by these domestic small businesses due to the loss of these trading partners.

To be timely, interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the above issues as indicated in the **DATES** section of this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, the IFR was effective on December 12, 2003. The agency will address comments on the identified set of issues that are received during this reopened comment period and were received during the previous comment period that closed on December 24, 2003, and will confirm or amend the IFR in a final rule. The agency, however, will not address any comments that have been previously considered during this rulemaking.



Dated: March 24, 2004

March 24, 2004.

Lester M. Crawford,
Acting Commissioner for Food and Drugs.

Dated: April 6, 2004

Robert C. Bonner,
Commissioner, Customs and Border Protection.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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